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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M0307	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP 03/08410	International filing date (day/month/year) 02.07.2003	Priority date (day/month/year) 02.07.2002
International Patent Classification (IPC) or national classification and IPC Int.Cl. A61K 31/58, 47/38, 9/107		
Applicant ALTANA Pharma AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 30.01.2004	Date of completion of this report 26.10.2004	
Name and mailing address of the IPEA/JP Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Authorized officer YUMIKO YAHARA	4C 9261
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I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
Nos. _____, as originally filed
Nos. _____, as amended (together with any statement) under Article 19
Nos. _____, filed with the demand
Nos. _____, filed with the letter of _____
- ☐ the drawings:
sheets/figs _____, as originally filed
sheets/figs _____, filed with the demand
sheets/figs _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-7</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-7</u>	NO
Industrial applicability (IA)	Claims	<u>1-7</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)**D1:WO 01/28563 A****D2:JP 62-192322 A**

The subject matter of claims 1-7 does not involve an inventive step over D1 and D2. D1 discloses aqueous pharmaceutical composition containing ciclesonide and hydroxypropylmethylcellulose 2910, wherein the ciclesonide is dispersed in an aqueous medium in the form of solid particles. D1 also indicates that hydroxypropylmethylcellulose 2910 not only avoids the variations in the concentrations of ciclesonide but also may function as stabilizer of the compositions. On the other hands, D2 mentions that autoclaving contributes to the sterilization of aqueous suspension of pregnanolone, a kind of steroids, which has an acetal moiety on its 17 position without any defradation.

Sterilization of of the composition is not specifically mentioned in D1, however, considering that a sterilized medicament is implicitly required in this technical field, a skilled person in the art would easily apply sterilization method mentioned in D2 to the ciclesonide-containing composition disclosed in D1.